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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,093	04/19/2001	Michael J. Coyne	PC10751A	3040

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Paul H. Ginsburg
Pfizer Inc
20th Floor
235 East 42nd Street
New York, NY 10017-5755

EXAMINER
MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
1631	6

DATE MAILED: 07/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/838,093	COYNE ET AL.	
	Examin r	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this c mmunication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Information Disclosure Statement

The IDS filed 2/26/02 has been considered in full.

Specification

The abstract of the disclosure is objected to because it is a single sentence fragment, and does not comprise a complete sentence. Appropriate correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "adequate" as recited in claims 1, 2, 7-8, and 10 is a relative term which renders the claim indefinite. The term "adequate" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Page 7 of the specification sets forth definitions for several terms, but does not define what applicant means by "adequate" with regard to immune memory or antibody titer. It is noted that claim 5, in step (a), defines an "adequate" antibody titer to be "at least about 2" for a particular disease, therefore recitation of the term "adequate"

with regard to an antibody titer does not render claim 5 indefinite. Claim 5, in step (c), also defines an "adequate anamnestic response" to be one of at least about a 4-fold increase in serum antibody titer, therefore recitation of the term "adequate" with regard to an anamnestic response does not render claim 5 indefinite. Claim 10 also recites an "adequate antibody titer" and an "adequate anamnestic response" in step (a). However, claim 10 does not depend from claim 5, and it is unclear if the "adequate" titer and anamnestic response of claim 10 are the same as those of claim 5. In addition, claim 10 recites an "adequate cellular titer", which is not defined anywhere. A definition of "adequate" in conjunction with immune memory and/or an antibody titer and/or cellular titer is not found in the instant specification. As one skilled in the art would not know the metes and bounds intended by applicant for an "adequate" immune response or an "adequate" cellular titer, or, in claim 10, for an "adequate" antibody titer or anamnestic response, the claims are indefinite.

Claim 5 recites the limitation "the sufficient anamnestic response" in step (d). There is insufficient antecedent basis for this limitation in the claim, therefore the claim is indefinite. Also, it is unclear is a "sufficient" anamnestic response is intended to be the same as an "adequate" anamnestic response, as recited in step (c), therefore the claim is further indefinite.

The term "sufficient" in claims 5 and 10 is a relative term which renders the claim indefinite. The term "sufficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term

"adequate" with response to an anamnestic response is defined in step (c) of claim 5. A level of response deemed by applicant to be "sufficient" is not similarly defined, and it is unclear whether a "sufficient" response is intended to be the same as an "adequate" response, therefore the claims are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by OLSON et al. (IDS ref: Am. J. Vet Res. Sep. 1988, vol. 49, no. 9, pages 1460-1466).

OLSON teaches a method of determining a duration of "adequate" immune memory in dogs, wherein the dogs are selected from various animal hospitals and clinics, and the dogs are living in "the field" (see p. 1461), the dogs are vaccinated against CPV and CDV, at least some dogs are evaluated at least 12 months after the last vaccination (see p. 1463, Figures), and each dog has a vaccination record; dogs with an antibody titer above a certain level (i.e. with a marker of immunity), and those with a titer below are indicated differently, and duration of immune memory is determined using the indicators and vaccination records (Figures 8 and 10-12, and page 1465), thus anticipating claims 1 and 3-4. OLSON teaches that if humoral

antibody is detected, then passive (i.e. cellular) immunity is evident (p. 1464), therefore his measurement of antibody titer is inherently also measurement of cellular immunity, and claim 5 is anticipated.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by VOLTI et al. (IDS ref: Eur. J. Epidem. (1995) vol. 11, pages 217-219).

VOLTI teaches a method of determining the duration of "adequate immune memory" (i.e. protective immunity) in humans by selecting children from one or more clinics, wherein each child has been vaccinated with HBV, the time since a last vaccination (3rd dose) is at least one year, the children are not isolated (they are in a "field environment"), and each child has a vaccination record; each child is assigned an indicator of immune memory (pos. or neg. with regard to titer), and the duration of immune memory for each child is determined based on the indicators and vaccine record (p. 218, first para. and Table 1), thereby anticipating claim 1.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by YANG et al. (J. Epidem. (Aug. 1999) vol. 9, no. 4, pages 209-215).

YANG teaches a method of determining the duration of immunologic memory by selecting a plurality of human subjects from schools (clinics), wherein each subject was vaccinated with a rabies vaccine, none were isolated, at least some were evaluated at a time since last vaccination of at least a year (see page 211, Table 1), and each subject has a vaccine record; subjects with seroconversion (a marker of immunity) are indicated

as positive responders while subjects that do not seroconvert are indicated as negative responders, and the duration (endurance) of immune memory is determined from the indicators and vaccination records of the subjects (p. 212 and Table 4), thereby anticipating claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over OLSON et al. . (IDS ref: Am. J. Vet Res. Sep. 1988, vol. 49, no. 9, pages 1460-1466) in view of SIMONSEN et al. (IDS ref: Vaccine (1987) vol. 5 no. 2, pp. 115-122) and DODDS (US 6,287,254, filed 11/2/1999).

Claim 1 recites a method of determining a duration of an "adequate" immune memory induced by a vaccine for a disease in an animal wherein a plurality of animals is selected from one or more clinics, wherein each animal has been vaccinated, the time since last vaccination is at least about one year, the animal had been living in a field environment for at least about one year since the last vaccination, and each animal has a vaccine administration record; each animal with a marker for immunity is assigned an indicator, each animal without the marker for immunity is assigned a second indicator; and the duration of "adequate" immune memory is determined from the indicators and vaccine administration record. Claim 2 limits the method to one wherein the duration of "adequate" immune memory is calculated using an estimation equation, wherein the estimation equation is derived by logistic regression of the indicators and vaccination record. Claims 3 and 4 limit the animal to a companion animal, specifically a dog or cat. Claim 7 limits the step of determining a duration of immune memory to determining the enrollment date of an animal, assigning variables denoting length of time between an enrollment date and a start of study date, and between a last vaccination date and an enrollment date, and use of logistic regression to determine an estimation equation comprising the variables, for determining the duration of immune memory. Claims 8 and 9 limit the estimation equation to a specific equation with particular constants. Claim 10 limits the method of claim 1 to one wherein animals are assigned to high risk and low risk categories based on the indicators assigned in claim 1.

OLSON teaches a method of determining a duration of "adequate" immune memory in dogs, as set forth above. OLSON teaches statistical analysis, specifically

regression analysis, of his data and correlation between a "marker for immunity" indicator (e.g. antibody titer) and duration of immune response (pp. 14-15), but does not teach use of logistic regression.

DODDS teaches that logistic regression is a statistical technique used in predicting disease occurrence and to explore relationships between specific diseases and vaccination (col. 7, lines 19-32).

SIMONSEN teaches specific regression equations for determining duration of immunity wherein the equations comprise variables for intervals (time) since last vaccination (pp. 116-117), and teaches that his data also comprises time since enrollment (Table 1).

It would have been obvious to one of ordinary skill in the art at the time of invention to have used logistic regression, and regression equations derived therefrom, as taught and suggested by DODDS and SIMONSEN, to determine a duration of immune memory induced by a vaccine against CPV and CDV in the method of OLSON, where the motivation would have been to use regression analysis equations to correlate the possibility of disease occurrence over time (wherein duration of immunity indicates a low possibility) with a vaccination record, as taught by both DODDS and SIMONSEN. One skilled in the art would reasonably have expected success in using logistic regression and equations derived therefrom to determine a duration of immune memory in the method of OLSON because both OLSON and SIMONSEN teach regression analysis of vaccination and indicator data, and DODDS teaches that logistic regression is a statistical technique which may be applied to vaccination data. It would further have

been obvious to have assigned animals to "high risk" and "low risk" categories in the method of OLSON based on antibody titer where the motivation would have been to differentiate animals with active immunity from those with "vaccination failures", as taught by OLSON (pp. 1464-1465).

Claims 1, 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over SIMONSEN et al. (IDS ref: Vaccine (1987) vol. 5 no. 2, pp. 115-122).

The claims recite a method of determining a duration of an "adequate" immune memory induced by a vaccine for a disease in an animal, as set forth above. Claim 5 limits the assigning of indicators to the steps of evaluating a blood sample from an animal that has not shown signs of the disease since the last vaccination date to detect an antibody titer of at least 2, administering a booster dose of vaccine to each animal that does not display an "adequate" antibody titer, re-evaluating animals within 3-28 days after receiving the booster dose to detect an anamnestic response of at least a 4-fold increase in antibody titer, and assigning the indicator for "no marker for immunity" to animals which showed signs of the disease, do not have an "adequate" antibody titer upon first evaluation and do not show the anamnestic response after booster; and assigning the "marker for immunity" indicator to animals which do display an "adequate" antibody titer and/or the anamnestic response after booster.

SIMONSEN teaches a method for determining duration of immunity in humans after vaccination against tetanus, wherein the humans are chosen from a variety of "clinics", have been vaccinated more than one year prior to evaluation, have been living

"in the field", and have vaccine administration records (p. 115 and 119 and Table 2 and 4). SIMONSEN teaches that immunity to tetanus corresponds to antitoxin concentrations (i.e. antibody titer) of at least 0.01 IU/ml, and that people with levels below this are considered susceptible to tetanus (pp. 115 and 121). SIMONSEN also teaches revaccination of people with low antitoxin concentrations and retesting after 4 weeks (i.e. 28 days), wherein at least some patients showed a 4-fold increase in antitoxin (pp. 119-120 and Figure 5). SIMONSEN does not specifically teach assigning people indicators and/or a "risk" status based on antitoxin concentration (indicator of immune memory).

It would have been obvious to one of ordinary skill in the art at the time of invention to have assigned "immune memory" and/or "risk" indicators to the patients in the method of SIMONSEN where the motivation would have been to easily differentiate those people at risk for tetanus vs. those not at risk, as suggested by SIMONSEN's discussion of individual risk of susceptibility to the disease as indicated by antitoxin concentration (p. 121).

Conclusion

Claims 1-10 are rejected; the abstract is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

mam
July 23, 2003